REMARKS

Claims 1-4, 6-13, 19-21, 23-25, and 27-29 are pending in the subject application. Applicant has added claims 30-31. Applicants maintain that these amendments do not raise any issue of new matter. Accordingly, upon entry of this amendment, claims 1-4, 6-13, 19-21, 23-25, and 27-31 will be pending.

Support for the new claims 30-31 may be found, inter alia, at page 9, lines 5-7 and page 15, lines 29-32 of the subject application.

Claim Rejections - 35 U.S.C. §112, second paragraph

In the April 13, 2010 Office Action the Examiner rejected claims 1-4, 6-13, 19-21, 23-25, and 27-29 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserted that the lack of a distinct definition for the term "substantially precedes" contains "no description of how much time (minutes, days, weeks, months, years?)" elapses between administration of mitoxantrone and the glatiramer acetate regimen. See April 13, 2010 Office Action at page 3. The Examiner further asserted that the term is open, broadly claimed, and not commensurate in scope with the support noted in the subject application.

In response, claim 1 is clear in view of the specification and particularly Example 1 of the subject application where applicant discloses treatment by infusion of mitoxantrone "at [m]onths 0, 1 and 2" and daily treatment with glatiramer acetate "two weeks after the last scheduled infusion." Further, this example clearly describes "short-term immunosuppression with mitoxantrone … followed by chronic treatment with Glatiramer Acetate." See specification at page 15. Thus, in this example the three mitoxantrone treatments precede the glatiramer acetate treatment

by approximately 2, 6, and 10 weeks respectively. Successful results of this example have been noted and are on the record. See Vollmer et al., *Multiple Sclerosis* 2008; 14: 663-670.

Applicant respectfully submits that the Examiner asserted an unreasonably broad interpretation of the claim. The MPEP requires that claims be given "their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art." See MPEP section 2111, citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), internal quotes omitted. Additionally, this analysis is not limited to a question of whether or not there is a distinct definition for a given term in the specification; rather the inquiry should "tak[e] into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." See MPEP section 2111, citing *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), emphasis added.

The pending claims, when read as a whole and in the context of the written description of applicant's specification, are both clearly defined and commensurate in scope with the disclosure. The claims clearly call for successive treatment first with mitoxantrone, then with glatiramer acetate. Thus, any interpretation of "substantially precedes" that is effectively co-administration is unreasonable in view of the specification. Additionally, the claims are clearly directed at a single treatment method and thus any interpretation of "substantially precedes" that is effectively two unrelated treatments also is unreasonable in view of the specification.

Applicant submits that one skilled in the art would be aware of the nature and limitations of the treatments as well as of the natural variability that exists from patient to patient and over the course of the disease in any given patient. A precise

numerical range, therefore, is unable to capture the full scope of the invention to which applicant is entitled. Applicant further submits that one skilled in the art could, from the material disclosed, readily design a treatment as described and claimed. Likewise, one skilled in the art would understand and be on clear notice if a proposed method fell within the metes and bounds of the claim as written.

Accordingly, applicant submits that the invention is both particularly pointed out and distinctly claimed as it would be understood by one skilled in the art. Applicant further submits that, when given its broadest reasonable interpretation, the claim language is fully commensurate in scope with the disclosure provided. Therefore, applicant respectfully submits that the objection to claims 1-4, 6-13, 19-21, 23-25, and 27-29 under 35 U.S.C. §112, second paragraph, has been overcome and requests that it be reconsidered and withdrawn.

New claims 30-31 define the period between mitoxantrone and glatiramer acetate administration in numerical terms. Page 15, lines 29-32 of the specification discloses the details of their treatment regimen, i.e., IV infusion of mitoxantrone at Months 0, 1 and 2 followed by daily subcutaneous injections of glatiramer acetate two weeks after the last scheduled infusion of mitoxantrone. In this disclosure the three mitoxantrone treatments precede the glatiramer acetate treatment by approximately 2, 6, and 10 weeks, respectively. Applicant, therefore, submits that for these reasons, as well as those described for claims 1-4, 6-13, 19-21, 23-25, and 27-29 above, claims 30-31 are not subject to the rejection under 35 U.S.C. §112, second paragraph.

Claim Rejections - 35 U.S.C. §103(a)

In the April 13, 2010 Office Action the Examiner rejected claims 1-4, 6-13, 19-21, 23-25, and 27-29 under 35 U.S.C. §103(a) as

allegedly unpatentable over Szabo et al. (US 6,531,464) in view of Arnon et al. (US 6,214,791) and Kerwar et al. (US 4,617,319). The Examiner asserted that this rejection was maintained because "the use of mitoxantrone and glatiramer acetate, alone (which is really what the method is now, since "substantially precedes" could mean any time frame before of the former before the latter) or in combination, for MS treatment, is known." See April 13, 2010 Office Action at page 4.

In response, applicant respectfully submits that a reasonable interpretation of the term "substantially precedes," viewed in light of the specification, would make this rejection moot. Accordingly, applicant respectfully submits that the objection to claims 1-4, 6-13, 19-21, 23-25, and 27-29 under 35 U.S.C. §103(a) has been overcome and requests that it be reconsidered and withdrawn.

Applicant submits that new claims 30-31 are not subject to this rejection because, as the Examiner has appreciated, the prior art fails to teach or suggest the successive treatment as recited in these claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed $440.00 fee for filing 2 new claims, is deemed necessary in connection with the filing of this response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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